EXHIBIT B

GYNECARE TVT*

Obturator System

Tension-free Support for Incontinence

GYNECARE TVT* *obturatorsysteem*
Spanningsvrij steunbandje tegen incontinentie

GYNECARE TVT* *obturatorsystem*
Spændingsfri støtte til inkontinens

GYNECARE TVT* *-obturaattorijärjestelmä*
Jännityksetön tuki inkontinenssin hoitoon

Système obturateur GYNECARE TVT*
Dispositif sans tension contre les incontinences

GYNECARE TVT* *Obturator System*
Spannungsfreie Unterstützung bei Inkontinenz

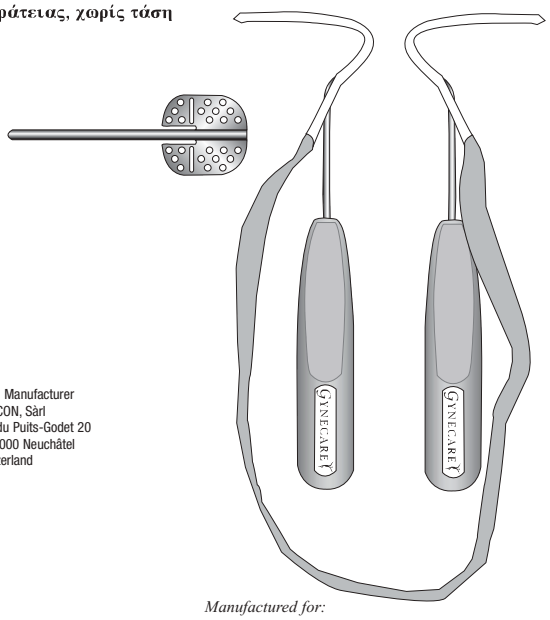
Sistema otturatorio GYNECARE TVT*
Dispositivo tension-free per l'incontinenza

Sistema obturador GYNECARE TVT*
Apoio sem tensão para incontinência

Sistema obturador GYNECARE TVT*
Protector sin tensión para la incontinencia

GYNECARE TVT* *obturatoriabandsystem*
Tensionsfritt stöd för behandling av inkontinens

Σύστημα επιπωματικού GYNECARE TVT*
Σύστημα υποστήριξης για την αντιμετώπιση της ακράτειας, χωρίς τάση



EC
Legal Manufacturer
ETHICON, Sàrl
Rue du Puits-Godet 20
CH-2000 Neuchâtel
Switzerland

Manufactured for:

GYNECARE WORLDWIDE
A division of ETHICON, INC.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

Made in Switzerland

RMC P18070/A

ENGLISH

GYNECARE TVT* *Obturator System*
Tension-free Support for Incontinence

GYNECARE TVT *Obturator* Device, Sterile Single Use

GYNECARE TVT *Obturator* Helical Passers, Sterile Single Use

GYNECARE TVT *Obturator* Atraumatic Winged Guide, Sterile Single Use

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

Important:

This package insert is designed to provide instructions for use of the GYNECARE TVT* *Obturator* System, including the GYNECARE TVT *Obturator* device, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT *Obturator* device. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION

The GYNECARE TVT *Obturator* System is a sterile, single patient use procedure kit consisting of:

GYNECARE TVT Obturator device

The GYNECARE TVT *Obturator* device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Color index Number 74160) PROLENE* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and that providing elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT Helical Passers

The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT *Obturator* device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT *Obturator* device. The Helical Passer MUST not be bent or deformed in any way.

GYNECARE TVT Atraumatic Winged Guide

The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

INDICATIONS

The GYNECARE TVT *Obturator* device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

INSTRUCTIONS FOR USE
(Note: hand positions shown in illustrations may vary)

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. Optionally, the labia may be sutured laterally to provide exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.
5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. *(See Figure 1)*

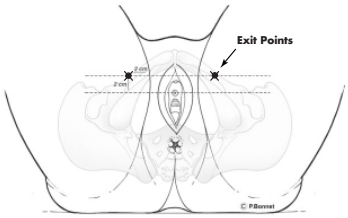


FIG. 1

6. Using Allis clamps for traction, make a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus.

   (Note: It is suggested that the device insertion be completed on one side before beginning dissection of the second side.)

   Using a "push-spread technique", begin blunt dissection preferably using pointed, curved scissors. The path of the lateral dissection should be oriented at a 45° angle from the midline, with the scissors oriented either on the horizontal plane or with the tips pointed slightly upward *(See Figure 2)*. Continue dissection toward the "junction" between the body of the pubic bone and the inferior pubic ramus. *(See Figure 2)*

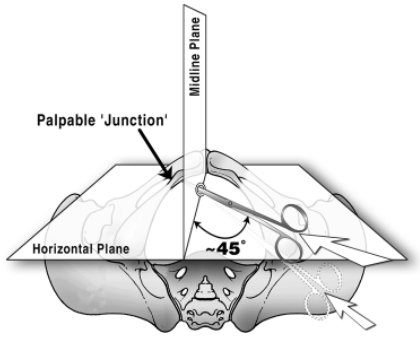


FIG. 2

   When the "junction" between the body of the pubic bone and the inferior pubic ramus is reached, perforate the obturator membrane. A loss of resistance can be felt when the membrane is perforated. The channel should be approximately 5–7 mm in diameter and no deeper than 5 cm. Dissection beyond 5 cm may allow unintended entry into the Space of Retzius. If the bone is not reached after dissecting 5 cm, re-evaluate that the angle of dissection is correct.

7. Remove the GYNECARE TVT Winged Guide from the package. *(See Figure 3)*

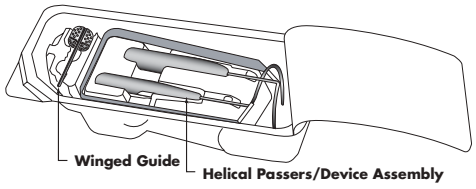


FIG. 3

8. Insert the GYNECARE TVT Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. Loss of resistance can be felt as the Winged Guide passes through the obturator membrane.

   If difficulty is encountered during insertion of the guide, reconfirm the direction of the tract with the scissors.

   (Note: The open side of the guide must be facing the surgeon. The bendable tab can be bent to increase the length of the guide if needed, See Figure 5.)